August 9, 2005

E. J. Rauckman, PhD, DABT,
for BASF Corporation
Toxicology and Regulatory Affairs
1201 Anise Court
Freeburg IL 62243

Dear Dr. Rauckman:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for EP-202MP (C4 alcohols, distillation residues; CAS No. 68551-11-1) posted on the ChemRTK HPV Challenge Program Web site on September 3, 2004. I commend BASF for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. The submitter's approach to these endpoints is reasonable. The submitter needs to provide robust summaries for biodegradation studies referenced in the test plan.

2. Health Effects. EPA agrees that adequate data are available for the acute toxicity endpoint for the purposes of the Challenge Program. However, EP-202MP is a complex mixture of C4-C16 alcohols, aldehydes, esters, and carboxylic acids with more than 50% of the components unidentified. Using data for 2-ethylhexanal, 2-ethylhexanol, n-butanol, butyraldehyde, and di-2-ethylhexyladipate to characterize the repeated-dose, genetic, and reproductive/developmental toxicity endpoints does not adequately address the complexity of the sponsored chemical mixture nor the potential interactions (e.g., additivity, synergism, or antagonism) among chemicals of different classes present in the mixture. Because of this complexity, it is not expected that the test data obtained from a subset of components in the mixture will adequately describe the properties of the mixture as a whole. Therefore, the use of the proposed representative substances is not supported for assessment of toxicity and the submitted data do not adequately address the health effects endpoints of the sponsored substance. The submitter needs to provide a combined repeated-dose/reproductive/developmental toxicity screening test of EP-202MP according to OECD TG 422 and in vitro gene mutation and cytogenetic assays of EP-202MP according to OECD TGs 471 and 473, respectively, to address these endpoints.

3. Ecological Effects.. EPA disagrees with the submitter that the submitted data are adequate. The submitter's approach for addressing ecotoxicity endpoints does not account for the contribution to aquatic toxicity of the 50-60% by weight of unidentified C8 and heavier components in EP-202MP. EPA believes that testing on the mixture would adequately characterize its aquatic toxicity. Therefore, fish, invertebrates, and algal toxicity data according to OECD TGs 203, 202 and 201, respectively, are

needed on EP-202MP.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that BASF advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to he following -email addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: M. E. Weber
N. Patel
J. Willis